510(k) vela® XL
Summary (Section 5)

APR - 6 2011

starmedtec
innovative solutions

K103654

510(k) summary of safety and effectiveness information according 21 CFR Part 807.87(h)

1. General Information:
   a. Applicant: StarMedTec GmbH
   Kreuzstrasse 22
   82319 Starnberg
   Germany
   +49815126861-0 (phone)
   +49815126861-35 (fax)

   b. Contact: Gregor Weidemann
   c. Date Prepared: November 16, 2010

2. Names:
   a. Device Name: vela® XL
   b. Common Name: vela® XL
   c. Classification Name: Laser instrument, surgical, powered
   d. Product code: GEX

3. Predicate Device:
   Lisa Laser Products – Revolix 120 Laser System (510(k) Number: K070476)

4. Product Description:
   The vela® XL is thulium laser system, which emits laser radiation with a wavelength of approximately 1.9 µm. The laser power transfers an optical application fiber. The indications are dissection, ablation, resection and coagulation of tissue.
   The laser system consists of:
   - laser system including control panel (user interface)
   - foot switch
   - application fiber

5. Indications for use:
   The vela® XL laser system including a fiber optic delivery system is intended to be used in surgical procedures such as open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft and hard tissue in medical specialities including:
   Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, Pulmonary, Gynaecology, ENT, Dermatology, Plastic Surgery and General Surgery

   Urology

   Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

   - Strictures of urethra and ureter
   - Bladder Neck Incisions (BNI)

- Ablation and resecetion of Bladder Tumors, Uretheral Tumors and Ureteral Tumors
- Ablation of Benign Prostatic Hyperplasia (BPH)
- Transurethral incision of prostate (TUIP)
- Holmium Laser Resection of the prostate (HoLRP)
- Holmium Laser Enucleation of the prostate (HoLEP)
- Holmium Laser Ablation of the prostate (HoLap)
- Condylomas
- Lesions or external genitalia

Gastroenterology

Open and endoscopic gastroenterological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder Calculi (Lithotripsy)
- Biliary/Bile duct calculi (Lithotripsy)
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non bleeding ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and malignant neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of Osler-Weber-Renu disease
- Vascular malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

Thoracic and Pulmonary

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue

- Laryngeal lesions
- Airway obstructions including carcinoma
- Polyps and granuloma
- Palliation of obstructing carcinoma of the tracheobroncial tree

Gynaecology

Open and endoscopic gynaecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis):

- Intra-uterine treatment of sub mucous fibroids
- Benign endometrial polyps and uterine septum by incision, excision and or vessel coagulation
- Soft tissue excision procedures such as excisional conisation of the cervix

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Endonasal / sinus surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal sinustomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery
- Lesions or tumours (oral, nasal, glossal, pharyngeal or laryngeal)
- Tonsillectomy
- Adenoidectomy

Dermatology and Plastic Surgery

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue, muscosal tissue, fatty tissue and cartilaginous tissue (hard tissue) including:

- Basal Cell Carcinomas
- Lesion of skin and subcutaneous tissue
- Skin tags
- Plantar warts

General Surgery

Open, laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystectomy
- Lysis of adhesion
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumours and lesions
- Complete or partial resection of internal organs, tumours, lesions

- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy
- Partial nephrectomy
- Pilonidal Cystectomy
- Resection of lipoma
- Debridement of decubitus ulcer
- Hemorrhoids
- Debridement of statis ulcer

Arthroscopy

Arthroscopic/orthopaedic surgery (excision, ablation, and coagulation of soft and cartilaginous (hard) tissue):

Ablation of soft and cartilaginous (hard) tissue in minimal invasive spinal surgery including

- Percutaneous laser disc decompression/disectomy
- Foraminoplasty
- Ablation and coagulation of soft vascular and non vascular tissue in minimally invasive spinal surgery

6. Performance testing:

The vela® XL is tested according to following standards:

IEC 60601-1:1988 + A1:1991 + A2:1995
IEC 60601-1-2:2005
IEC 60601-1-4: 1996 (First Ed.) + Am.1: 1999 (Consolidated 1.1 Ed.)
for use with IEC 60601-1 (1988), Amts 1 (1991) and 2 (1995)60601-1-6
IEC 60601-2-22:2005
IEC 60825-1:2007
IEC 62366:2007
IEC 62304:2007
The device also complies with European Medical Device 93/42/EEC + Amendment 2007/47/EC

7. Performance data

Laboratory testing was conducted to verify and validate that the vela® XL met all design specifications and is substantially equivalent to the predicate device.
Clinical data: No clinical information is required.

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8. Conclusion:

The vela® XL is as effective and save as the predicate device. The vela® XL is substantially equivalent to the cited legally marked predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

StarMedTec GmbH
% Mr. Gregor Weidemann
Kreuzstraß22
82319 Starnberg
Germany

APR - 6 2011

Re: K103654
Trade/Device Name: vela XL
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 7, 2011
Received: March 9, 2011

Dear Mr. Weidemann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): n.a.

Device Name: vela XL

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Prescription Use X AND/OR Over-The-Counter-Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103654

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Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

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Prescription Use___X____ AND/OR Over-The-Counter-Use_____
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510(k) Number K103654

- Non bleeding ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and malignant neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of Osler-Weber-Renu disease
- Vascular malformation
- Gastritis
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- Esophageal ulcers
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- Colitis
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Neil R P Ogden for mxm

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510(k) Number K103654

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Gynaecology

Open and endoscopic gynaecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis):

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Dermatology and Plastic Surgery

Prescription Use___X___ AND/OR Over-The-Counter-Use_____
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mam
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510(k) Number K103654

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- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy

Prescription Use___X____ AND/OR Over-The-Counter-Use_____
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510(k) Number K103654

- Partial nephrectomy
- Pilonidal Cystectomy
- Resection of lipoma
- Debridement of decubitus ulcer
- Hemorrhoids
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